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(80) Analysis method for determining substances from biological fluids.

(82) A test strip for analyzing substances from biological fluids is disclosed in which the matrix comprises a porous membrane having an asymmetric pore structure which is designed for application of the biological fluid to the large pore side of the membrane and in which a determination of the biological fluid is made on the opposite side of the membrane containing a small pore size. The membrane contains anionic surfactant in an amount of 1 to about 4% by weight based on the polymer casting solution used to form the porous membrane.

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## ANALYSIS METHOD FOR DETERMINING SUBSTANCES FROM BIOLOGICAL FLUIDS

Field Of The Invention

The present invention relates to test strips or test devices for analyzing substances from biological fluids in which the matrix comprises a porous membrane having asymmetric pore structure and designed for the application of the biological fluid to the large pore side of the membrane and making a determination on the opposite fine pore side of the membrane. The membrane contains anionic surfactant equivalent to surfactant addition of about 1 to about 4 percent by weight based on polymer casting solution.

10 Background Of The Invention

Test strips which contain reagents in a matrix of paper or plastic material and in which the sample is applied directly to this matrix have become extremely important for quick and simple analysis of individual samples. Measurement results which are the same as or better than wet chemical methods can be obtained.

However, the test strips commercially available to date for determining blood constituents frequently possess certain disadvantages. The erythrocytes contained in blood interfere with most methods. The user must therefore typically remove serum or plasma from whole blood by centrifuging before making an analysis. This, however, presents problems, particularly in the case of small sample amounts. With more recent testing agents the reagent layer itself (European Patent 0 064 710, DOS German Published Specification 34 07 395) or a covering membrane is semipermeable and retains the erythrocytes. Accordingly, the test systems can be directly loaded with whole blood. However, in these test systems hemoglobin has to be removed by wiping or washing off before reflection-photometry or visual analysis. This method cannot be used for analysis of large molecules, e.g., certain enzymes, because these are also retained by the semipermeable layer. In addition, the wiping-off process constitutes a potential source of dangerous infections because blood samples may occasionally be contaminated with hepatitis viruses or other pathogens.

In view of the requirement for high reproducibility of the diagnosis, test strips systems which have a very simple structure and are uncomplicated to produce with a few production steps are preferred.